SECTION 5 510(K) SUMMARY

510(k) Notification (21 CFR 807.90(e))

Traditional Premarket 510(k) Submission

OCT 16 2009

IdentEvent™

Date: July 2, 2009

Submitted by: Optima Neuroscience, Inc.
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Proprietary Name: IdentEvent™

Regulation Number: 21 CFR 882.1400

Classification Name: Electroencephalograph, Electroencephalogram (EEG) signal spectrum analyzer

Classification Code: OMB, OLT

Regulatory Class: II

Predicate Devices: Persyst Reveal® (K011397)
NeuroGuide Analysis System (K041263)

Description: Optima's IdentEvent™ analyzes digital scalp electroencephalograph (EEG) signals recorded from standard recording systems and displays information about brain electrical activity to the user. The application only analyzes and displays information from previously recorded digital EEG files. IdentEvent is designed for post-hoc EEG review of long-term EEG recordings, including the detection of seizure events.

IdentEvent requires previously recorded, digitized scalp EEG recordings with electrodes placed according to the standard 10/20 system. The recording can then be automatically analyzed to detect seizures which are then marked for review by the user. IdentEvent includes the following features (outputs):

- Display of raw & filtered EEG signals for review
- Display of the following quantitative EEG (qEEG) measures:
  - Amplitude Variation
  - Maximum Frequency
- Review (and possible deletion) of detected seizures
- Entry, editing and display of user-entered comments
- Graphical and text reports of detected seizures and comments

IdentEvent displays two measures for use in post-hoc analysis of EEG: Amplitude Variation and Maximum Frequency.

Amplitude Variation is the calculation of standard deviation of one EEG signal within each calculation window, a statistical measure which increases with larger signal peaks (amplitude changes). The Amplitude Variation for one signal is calculated as follows:

$$s = \sqrt{\frac{\sum_{i=1}^{N} (x_i - \bar{x})^2}{N-1}}$$

Maximum Frequency is the maximum number of one-directional (negative to positive) zero crossings among 11 overlapping 1 second time windows within a given window defined by the sample period (5.12 seconds).

Suppose that {x1, x2, x3, ..., x2048} represents a sample period of 5.12 second 400 Hz EEG epoch. Then 11 overlapping (600ms) 1 second windows can be constructed as:

W1 = {x1, x2, ..., x400}, W2 = {x161, x162, ..., x560}, W3 = {x321, x322, ..., x720}, ..., W11= (x1601, x1602, ..., x2000)

For each Wi, i=1, 2, ..., 11, frequency of one-directional (negative to positive) zero crossings is observed as fi, then the Frequency Maximum for this sample period is defined as:

$$\max_{1 \le i \le 11} f_i$$

The application will be used only by neurologists and EEG technicians who are trained in the interpretation of EEGs. The graphical user interface will be designed to be intuitive and easy to setup and use without the need for extensive user training.

Indications for Use:

IdentEvent™ is a software-only product with an algorithm intended to analyze previously acquired, adult (≥18 years) scalp EEG signals and mark events that may correspond to electrographic seizures for the purpose of reviewing prolonged EEG traces. The marked events are reviewed, possibly deleted, and interpreted by qualified clinical practitioners who will exercise professional judgment in using the information.

IdentEvent also includes the display of the quantitative EEG parameters Amplitude Variation and Maximum Frequency, which are intended to help the user analyze the EEG waveform after it has been collected.

IdentEvent requires the use of EEGs recorded with at least a 16-channel scalp montage following the standard 10/20 electrode placement system. IdentEvent does not provide any diagnostic conclusion about the patient's condition to the user.

Technological Characteristics:

Optima's IdentEvent marks events that may correspond to electrographic seizures for the purpose of reviewing prolonged EEG traces and displays quantitative EEG parameters to help the user analyze the EEG waveform after it has been collected. These characteristics may be viewed in comparison with the technological characteristics of the identified predicate devices in Table 5.1.

Table 5.1 Comparison of Device Characteristics

	Optima Neuroscience IdentEvent Software (K092039/A02)	**Persyst Reveal (K011397) Appendix A-01**	**Neuroguide Analysis System (K041263) Appendix A-02**
Identifies spikes	No	Yes	No
Identifies seizures	Yes	Yes	No
Displays calculated EEG measures	Yes	No	Yes
Calculated EEG measures displayed:	Amplitude Variation & Maximum Frequency	None	Power, Coherence & Fast Fourier Transform (FFT)
User-adjustable seizure detection	No	Yes	No
Users can add/delete events	Yes	Yes	No
Number of EEG channels	21 channels (standard 10/20 scalp EEG montage)	Unknown	Unknown
Type of EEG recording supported	Scalp EEG only	Unknown	Unknown
Type of EEG analysis	Post-hoc only	Post-hoc only	Post-hoc only
Population age	Adults (age > 18)	Unknown	Unknown
Product Code	OMB, OLT	GWS	GWQ, GWS
Indications for Use	See Section 4	See Section 12	See Section 12

Non-Clinical and Clinical Testing

Non-Clinical: The IdentEvent seizure detection algorithm relies upon underlying mathematical analyses, including signal regularity, maximum frequency, and amplitude variation. Each mathematical analysis was independently calculated and verified against results generated from published methods.

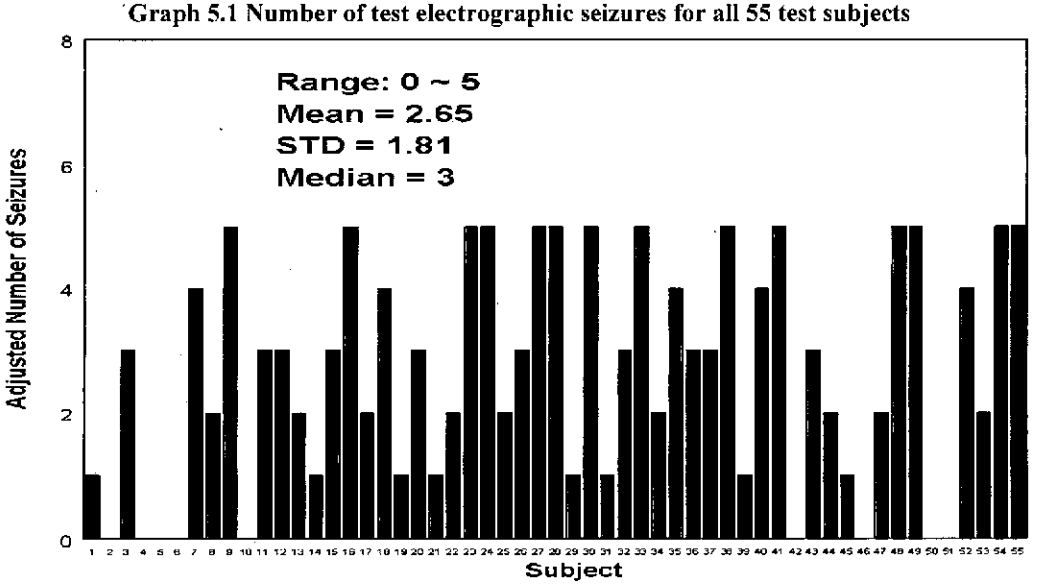
Clinical: Optima conducted an extensive clinical test to: 1) Evaluate the positive percent agreement (i.e., detection sensitivity based on independent EEG review panel) and negative percent agreement (i.e., false detection rate based on independent EEG review panel) of Optima's IdentEvent on long-term scalp EEG recordings; and, 2) Demonstrate the seizure detection performance, in terms of positive percent agreement and negative percent agreement, of Optima's IdentEvent is equal to or better than those of Persyst Reveal.

Subject Population and Test Dataset

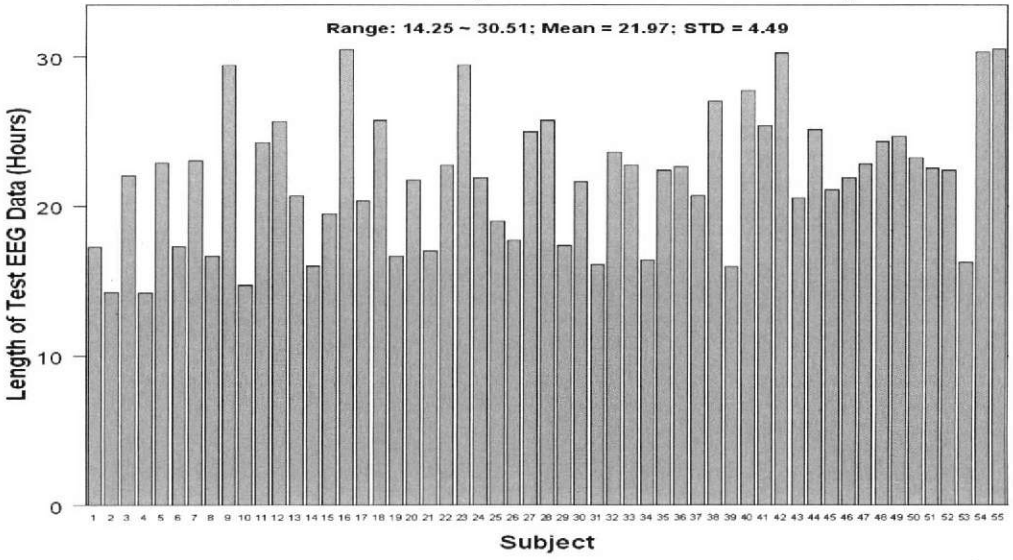
The seizure detection performance of IdentEvent's algorithm was evaluated on scalp EEG recordings from patients with medically refractory seizures. All patients 18 years of age or older with a history of intractable seizures admitted to multiple clinical sites for long term EEG-video recordings for diagnostic or pre-surgical evaluation were asked to participate.

A total of 436 EEG segments sampled from 55 long-term scalp EEG recordings were included in the test dataset. These 55 recordings (from 55 patients) represented the first 50 recordings with at least one seizure recorded and the first 5 without seizures recorded (based on initial clinical reports). Under the constraint that no more than 3% of the total seizures were included from one subject; detection performance was tested on 146 seizures in a total of 1,208.24 hours of scalp EEG recordings from these 55 patients. Otherwise, no additional inclusion/exclusion criteria were applied in the data selection process. The number of seizures for all the test subjects is shown in Graph 5.1 and the number of hours for each of the samples may be viewed in Graph 5.2.

Graph 5.1 Number of test electrographic seizures for all 55 test subjects



Graph 5.2 Number of sampled EEG hours for all 55 test subjects



Reference Standard

Each of the 436 sampled EEG segments was reviewed by three independent, blinded EEG experts (all neurologists/epileptologists) to identify electrographic seizures. The end point of this independent review was to identify, if any, the seizure onset times in each of the sampled EEG segments.

Due to the anticipated inter-rater variability among EEG experts, a majority rule (at least 2 out of 3) was applied to make the final determination of "true" electrographic seizure events.

Statistical Analysis

1) Inter-Rater Variability

Inter-rater variability was assessed using Cohen's kappa statistic between any pair of EEG experts. The pair-wise kappa statistics among pairs of experts range from 0.641 to 0.790, with a weighted average of 0.680. Based on the interpretation of kappa statistic by Landis and Koch (Biometrics 33: 159-174, 1997), the kappa statistics for all pairs of EEG reviewers indicated "substantial agreement" (0.61 ~ 0.80).

2) Detection Performance

Based on the seizure samples determined by the independent EEG review panel, the positive percentage agreement (i.e., detection sensitivity based on the Reference Standard) and negative disagreement rate (i.e., false detection rate based on the Reference Standard) were estimated for both IdentEvent and the predicate device. Bootstrap method was applied to construct 95% confidence intervals for the estimated performance statistics, as well as to statistically compare positive percentage agreement between IdentEvent and the predicate device. In addition, Wilcoxon signed-rank test (non-parametric paired two-sample t-test) was applied to compare negative disagreement rates between the two detection devices.

Results – Summary
Table 5.2 provides a summary of the detection performance statistics for IdentEvent and Reveal.

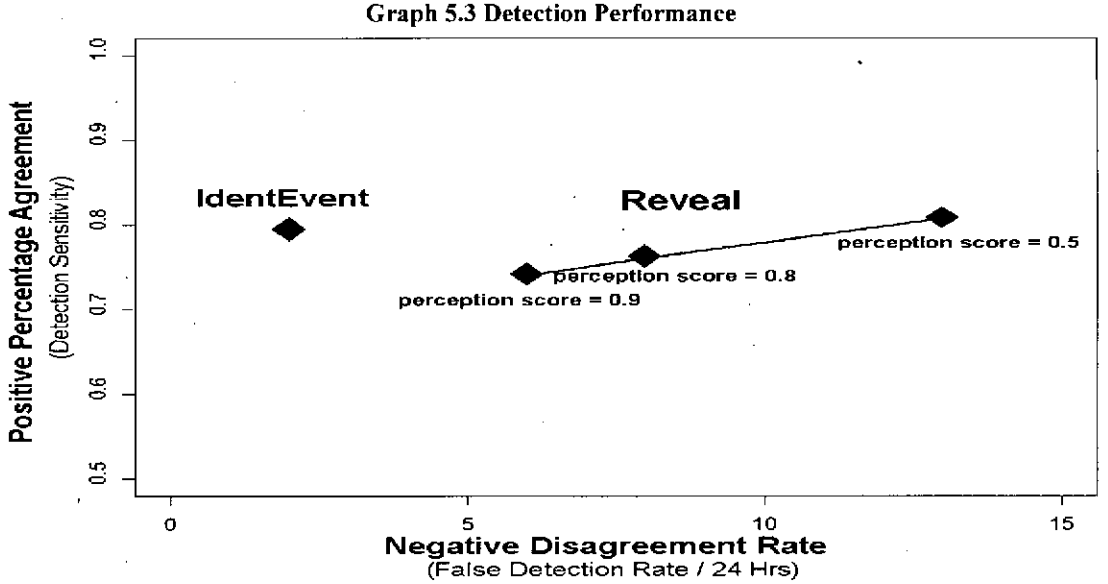
Table 5.2 Summary of Detection Performance Statistics

	IdentEvent	Reveal (0.5)	Reveal (0.8)	Reveal (0.9)
Positive % Agreement (95% C. I.)	79.5% (70%, 87%)	80.8% (72%, 88%)	76.0% (66%, 84%)	74.0% (64%, 83%)
Negative Disagreement Rate (95% C. I.)	2/24h (1.3, 3.3)/24h	13/24h (10.1, 17.1)/24h	8/24h (5.8, 10.5)/24h	6/24h (4.1, 7.8)/24h

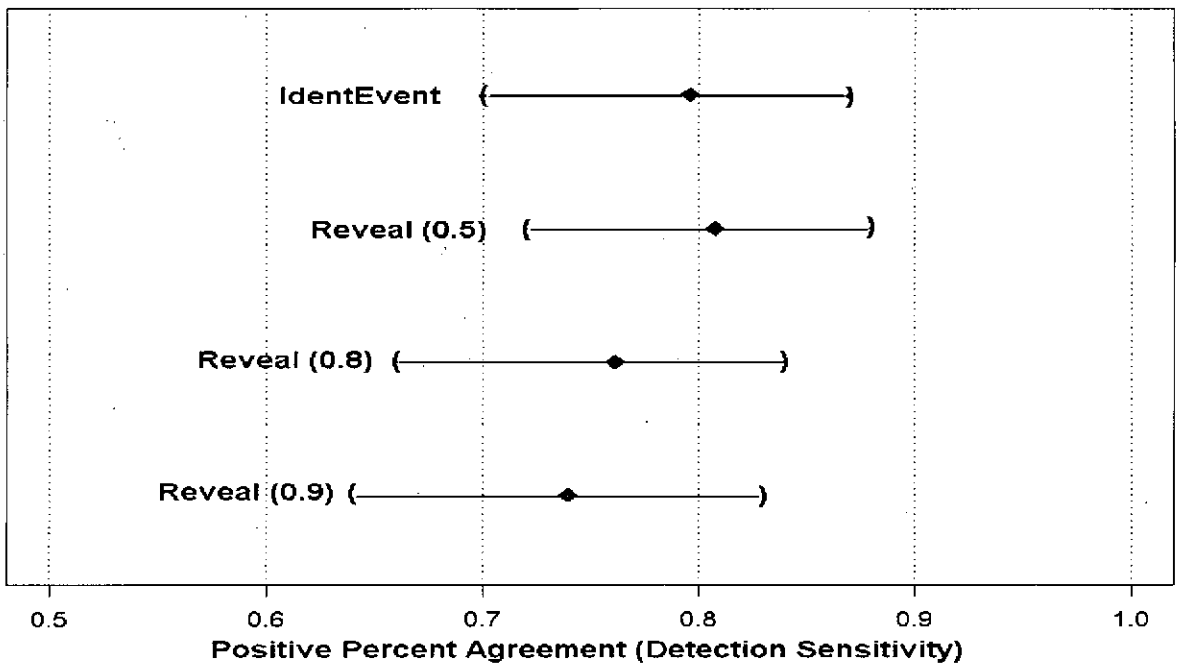
Results – Detailed
The overall seizure detection positive percent agreement of IdentEvent was 79.5% (bootstrap 95% CI = [70%, 87%]) with a negative disagreement rate of 2 per 24 hours (bootstrap 95% CI = [1.3, 3.3]). The positive percent agreements of Reveal were 80.8%, 76%, and 74% (bootstrap 95% CIs = [72%, 88%], [66%, 84%], [64%, 83%], respectively) using its three detection thresholds (perception score = 0.5 (default), 0.8 and 0.9), respectively. Reveal's negative disagreement rates were 13, 8, and 6 per 24 hour (bootstrap 95% CIs = [10.1, 17.1], [5.8, 10.5], [4.1, 7.8], respectively).

The statistical comparisons to the predicate device were based on a type I error of .05 and a .10 non-inferiority margin. A Wilcoxon signed rank test and bootstrap estimates to generate 95% confidence intervals were calculated. A plot of negative disagreement rate (on the X-axis) and positive percent agreement (on the Y-axis) is given in Graph 5.3. Confidence intervals for positive percent agreement and negative disagreement rate are presented in Graphs 5.4 and 5.5. IdentEvent has similar positive percent agreement to the predicate while the negative percent agreement is significantly higher suggesting the false detection rate is lower with IdentEvent.

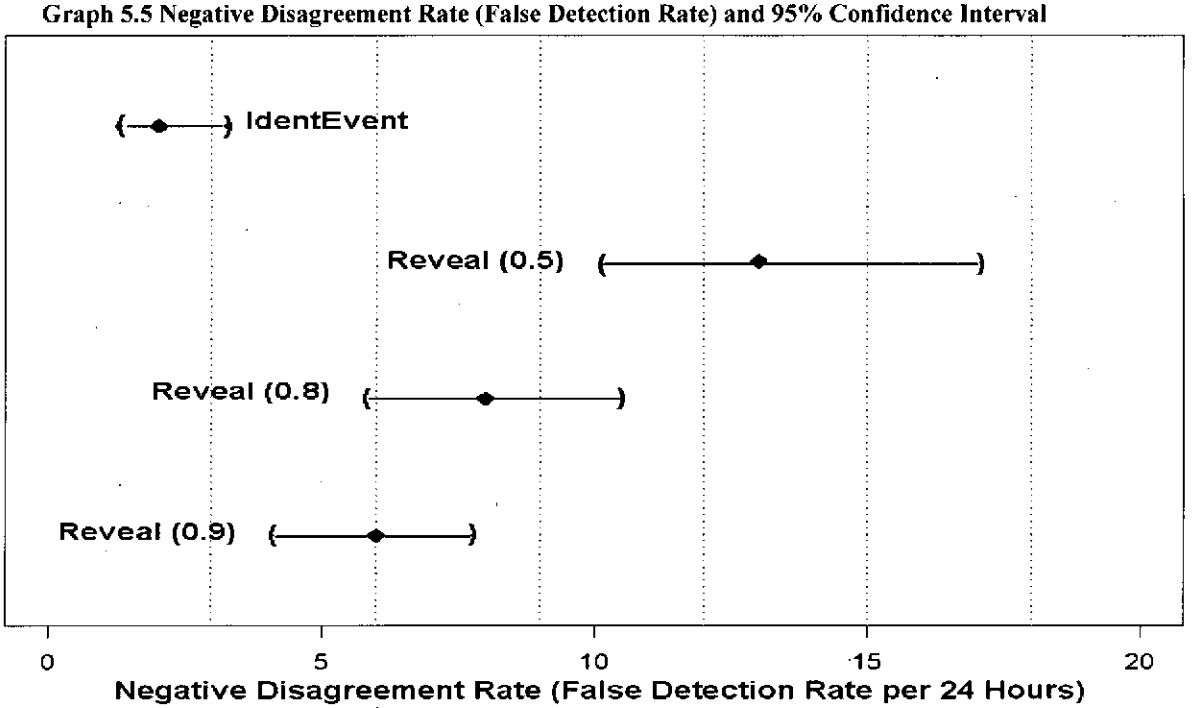
Graph 5.3 Detection Performance



Graph 5.4 Positive Percent Agreement (Detection Sensitivity) and 95% Confidence Interval



Graph 5.5 Negative Disagreement Rate (False Detection Rate) and 95% Confidence Interval



Safety testing was performed during validation testing off all software requirements which included safety requirements. Safety requirements included proper handling of patient information, checking data integrity, and prompt notification of the user upon detection of abnormalities. Validation tests demonstrated that all safety requirements were met.

A copy of all study data may be found in Appendix A-05.

Conclusion
Compared to Persyst Reveal, Optima's IdentEvent is substantially equivalent in safety and performance, including sensitivity (positive percent agreement) and false positive rate (negative percent agreement).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Optima Neuroscience, Inc.
c/o Ms. Paula Wilkerson RAC, CRA
Actualized Science, LLC
12337 NW 9th Lane
Newberry, FL 32669

OCT 16 2009

Re: K092039
Trade/Device Name: IdentEvent™ Version 1.0H
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OMB, OLT
Dated: July 2, 2009
Received: September 17, 2009

Dear Ms. Wilkerson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092039

Device Name: IdentEvent™ (Version 1.0H)

Indications For Use:

IdentEvent™ is a software-only product with an algorithm intended to analyze previously acquired, adult (≥18 years) scalp EEG signals and mark events that may correspond to electrographic seizures for the purpose of reviewing prolonged EEG traces. The marked events are reviewed, possibly deleted, and interpreted by qualified clinical practitioners who will exercise professional judgment in using the information.

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IdentEvent requires the use of EEGs recorded with at least a 16-channel scalp montage following the standard 10/20 electrode placement system. IdentEvent does not provide any diagnostic conclusion about the patient's condition to the user.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sara Doll

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K092039